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NOTICE OF ALLOWANCE AND FEE(S) DUE

21839 7590 05/01/2009 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404

| EXAMINER | | | | | | |
|----------------|--------------|--|--|--|--|--|
| WATTS, JENNA A | | | | | | |
| ART UNIT | PAPER NUMBER | | | | | |
| 1794 | | | | | | |

DATE MAILED: 05/01/2009

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | |
|---|-------------|----------------------|---------------------|------------------|--|--|
| 10/577,553 | 04/28/2006 | Suk-Hyung Kwon | 007077-000019 | 8311 | | |
| TITLE OF INVENTION: METHOD FOR PREPARING SOPHORAE FRUCTUS EXTRACT CONTAINING ISOFLAVONE | | | | | | |

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO | \$1510 | \$300 | \$0 | \$1810 | 08/03/2009 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION NOT THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

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If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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| | | | | | | | (Signature) |
| | | | | | | | (Date) |
| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENTOR | | ATTO | RNEY DOCKET NO. | CONFIRMATION NO. |
| 10/577,553 TITLE OF INVENTION | 04/28/2006 : METHOD FOR PREP. | ARING SOPHORAE FR | Suk-Hyung Kwon UCTUS EXTRACT CON | TAINING ISOFLA | | 07077-000019 | 8311 |
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| EXAM | IINER | ART UNIT | CLASS-SUBCLASS | | | | |
| WATTS, | JENNA A | 1794 | 426-655000 | | | | |
| CFR 1.363). Change of corresp Address form PTO/S1 Fee Address" ind PTO/SB/47; Rev 03-C Number is required. ASSIGNEE NAME A | ND RESIDENCE DATA less an assignee is ident h in 37 CFR 3.11. Comp | nge of Correspondence "Indication form ed. Use of a Customer A TO BE PRINTED ON | 2. For printing on the p (1) the names of up to or agents OR, alternati (2) the name of a single registered attorney or a 2 registered patent atto listed, no name will be THE PATENT (print or ty) data will appear on the p TT a substitute for filing an | 3 registered patent rely, e firm (having as a sgent) and the name meys or agents. If a printed. te) tet | membes of uno nan | er a 2 | ocument has been filed for |
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| - 11 | s SMALL ENTITY state | is. See 37 CFR 1.27. | ☐ b. Applicant is no lon | | | | |
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| 21839 7. | 590 05/01/2009 | | EXAMINER | | |
| BUCHANAN, II | NGERSOLL & ROO | WATTS, JENNA A | | | |
| POST OFFICE BOX 1404 | | | ART UNIT PAPER NUMBI | | |
| ALEXANDRIA, V | /A 22313-1404 | 1794 | | | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 673 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 673 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Application No. Applicant(s) 10/577.553 KWON ET AL. Notice of Allowability Examiner Art Unit JENNA A WATTS 1794 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to . 2. The allowed claim(s) is/are 1-8. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). b) ☐ Some* c) ☐ None of the: 1. A Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date Information Disclosure Statements (PTO/SB/08). 7. X Examiner's Amendment/Comment Paper No./Mail Date 20060428 8. X Examiner's Statement of Reasons for Allowance 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material Other .

/J. A. W./ Examiner, Art Unit 1794

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Examiner's Amendment and Reasons for Allowance

Claims 1-8 are allowed in the current application.

Examiner's Amendment

- An examiner's amendment to the record appears below. Should the changes
 and/or additions be unacceptable to applicant, an amendment may be filed as provided
 by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be
 submitted no later than the payment of the issue fee.
- Authorization for this examiner's amendment was given in a telephone interview with Ms. Lisa Stahl on April 23, 2009.
- 3. The application has been amended as follows:
- 4. Amendment to the Specification of the Invention:
- Please amend the specification to read as follows:
- 6. Page 11, Line 10: Please amend the line to read as follows:
- -- Comparison of isoflavone [concentrations] concentrations in Sophorae Fructus extracts --
- Page 14, Line 9: Please amend the line to read as follows:
- -- Comparison of isoflavone [sentents] content in Sophorae Fructus extracts according to the temperature and time of hydrothermal extraction --

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8. Page 17, Line 5: Please amend the line to read as follows:

-- We investigate the effect of ethanol treatment on Sophorae Fructus extracts --

9. Amendment to the Title of the Invention:

Please amend the title to read as follows:

-- Method for Preparing an Extract of Fruit of Sophora japonica Containing Isoflavone --

10. Amendment to the Claims:

Please amend the following claims to read as follows:

Claim 1. A method for preparing [a-Sepherae-Fructus-extract) an extract of a fruit of Sophora japonica containing isoflavone comprising the following steps: (a) hydrothermally extracting (Sepherae-Fructus) the fruit of Sophora japonica by adding water to the [Sepherae-Fructus] fruit of Sophora japonica and heating; (b) removing a precipitate by cooling and filtering the extract to produce a filtrate; (c) treating the filtrate with amylase or pectinase; (d) recovering a precipitate by centrifuging the enzyme treated solution and adding ethanol to the precipitate; and (e) recovering a supernatant by centrifuging the ethanol added solution.

Claim 2. The method of claim 1, wherein the [Sephorae Fructus] fruit of Sophora japonica of step (a) is used after pulverization.

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Claim 3. The method of claim 1, wherein the hydrothermally extracting of step (a) is performed at 100 - 130°C [440-430°C] for 1 - 6 [4-6] hours after adding 3 - 20 parts water per 1 part fruit of Sophora japonica (w/w) to the fruit of Sophora japonica

Claim 4. The method of Claim 1, wherein the extract of step (b) is cooled to 40-60 [40_-60]*C.

Claim 5. The method of Claim 1, wherein the step (e) is performed by heating the filtrate to 40 - 60 [40-60]*C, adding amylase or pectinase to [by] 0.01 - 1 [0.04-4] % (v/v) to the filtrate, and reacting the filtrate for 4 - 24 [4-24] hours.

Claim 6. The method of Claim 1, wherein the precipitate of step (d) is shaken for 30 - 60 [30-60] minutes after adding 5 - 10 parts ethanol per 1 part precipitate (w/w) to the precipitate (ethanol 5-10 times as much as the precipitate weight), and left for 60 - 120 [60-420] minutes.

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Reasons for Allowance

11. The following is an examiner's statement of reasons for allowance:

12 The closest prior art of record relating to the Sophora japonica plant. Lanzendorfer et al. (U.S.P.A. 2002/0142012), Liviero et al. (U.S.P.A. 2002/0041907) and Erdelmeier (U.S.P.A. 2003/0180394) all teach that it was known to make extracts from Sophora japonica and that the Sophora japonica plant contains isoflavones and/or flavinoids. However, neither Lanzendorfer nor Liviero disclose the method of preparing such an extract, and Liviero et al. teaches that the extracts from Sophora japonica are preferably made from the green leaves of the plant. Erdelmeier teaches that an extract can be made from the roots of plants from the Sophora species such as Sophora japonica and teaches a method using ethanol extraction and drying. Neither of the above mentioned prior art teach using the fruit of the Sophora japonica plant, nor do they teach the method of the instant application which comprises the steps of hydrothermally extracting the Sophorae Fructus, fruit of Sophora japonica Linne as per Applicant's specification, removing a precipitate by cooling and filtering, treating the filtrate with amylase or pectinase, centrifuging the enzyme treated solution and adding ethanol to the precipitate and recovering the supernatant by centrifuging the ethanol added solution.

The closest prior art of record relating to the method of extracting isoflavone,
 Shen et al. (U.S. Patent No. 5,851,792), teaches a method of making an aglucone

isoflavone enriched whey material and extract, comprising the steps of adding glucoamylase or pectinase to soybean whey slurry, centrifuging the soybean whey to recover a precipitate and adding ethanol to the precipitate recovered. Shen et al. does not teach hydrothermal extraction, cooling and filtering the hydrothermally extracted solution, treating the resulting filtrate with enzyme and recovering a supernatant by centrifuging the ethanol containing solution. It would have been non-obvious to add all of these steps to the method of Shen in order to arrive at the claimed method of the instant application.

- 14. Thus, a method for making an extract from the Sophorae Fructus, fruit of Sophora japonica, by hydrothermally extracting and filtering the fruit, contacting the filtrate with amylase or pectinase and ethanol, and centrifuging the ethanol containing solution to obtain a supernatant, is free of the prior art.
- 15. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."
- 16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNA A. WATTS whose telephone number is (571) 270-7368. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

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17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

r atent Application information Netheval (1 Airt) system. Otatus information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. A. W./

J. Watts

Examiner, Art Unit 1794

April 23, 2009

/KEITH D. HENDRICKS/

Supervisory Patent Examiner, Art Unit 1794